K061598

510(k) Summary
HemosIL Homocysteine and HemosIL Homocysteine Controls

Submitted by:

Instrumentation Laboratory Co.
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SEP 22 2006

Summary Prepared:

June 7, 2006

Device Trade Name:

HemosIL Homocysteine
HemosIL Homocysteine Controls

Regulatory Information:

862.1377	Urinary homocysteine (nonquantitative) test system
LPS	Class II
862.1660	Single (specified) analyte controls (assayed and unassayed)
JJX	Class I

Identification of Predicate Device:

K992858	Abbott IMx Homocysteine

Device Intended Use and Description:

HemosIL Homocysteine is an automated latex enhanced immunoassay for the quantitative determination of total L-homocysteine in human citrated plasma on IL Coagulation Systems. Homocysteine (Hcy) values can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia or homocystinuria.

HemosIL Homocysteine Controls are assayed quality controls intended to monitor the accuracy and precision of HemosIL Homocysteine on IL Coagulation Systems.

Hcy levels in patient plasma are measured automatically on IL Coagulation Systems in three stages:

1. Reduction of mixed disulfides and protein-bound forms of Hcy present in the plasma samples to free Hcy.
2. Enzymatic conversion of free Hcy to S-adenosyl-L-homocysteine (SAH) by the SAH hydrolase (SAHH) in the presence of an excess of adenosine.
3. Competitive agglutination reaction between anti-SAH and SAH / conjugate.

The degree of agglutination is inversely proportional to the concentration of total Hcy in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

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Statement of Technological Characteristics of the Device Compared to Predicate Device:

HemosIL Homocysteine is substantially equivalent to the commercially available predicate device (Abbott IMx Homocysteine) in performance and intended use.

Summary of Performance Data:

Method Comparison

In a method comparison study evaluating 76 paired sodium citrate and EDTA patient plasma samples with homocysteine levels ranging from 4.2 to 56.7 µmol/L, the correlation statistics for HemosIL Homocysteine (sodium citrate plasma) versus the predicate device (EDTA plasma) are shown below:

IL System	Slope	Intercept	r
ACL Advance	0.8292	0.3503	0.9915

Precision

Within run and total precision assessed over multiple runs using two control levels and a plasma sample gave the following results:

ACL TOP	Mean (µmol/L)	CV% (Within run)	CV% (Total)
Hcy Control Level 1	11.4	2.0	4.8
Hcy Control Level 2	22.4	1.5	3.5
Hcy Plasma Sample	8.1	2.9	5.5

ACL ELITE/ELITE PRO/ 8/9/10000	Mean (µmol/L)	CV% (Within run)	CV% (Total)
Hcy Control Level 1	12.3	2.3	5.1
Hcy Control Level 2	22.8	4.3	6.2
Hcy Plasma Sample	8.4	2.6	5.9

ACL Futura/ACL Advance	Mean (µmol/L)	CV% (Within run)	CV% (Total)
Hcy Control Level 1	10.5	3.5	6.0
Hcy Control Level 2	21.1	2.6	3.5
Hcy Plasma Sample	7.9	3.5	5.6

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol Marble
Instrumentation Laboratory Company
113 Hartwell Ave.
Lexington
MA 02421

SEP 2 2 2006

Re: k061598
Trade/Device Name: HemosIL Homocysteine and
HemosIL Homocysteine Controls
Regulation Number: 21 CFR 862.1377
Regulation Name: Urinary homocystine (non-quantitative) test system
Regulatory Class: Class II
Product Code: LPS, JJX
Dated: August 21, 2006
Received: August 22, 2006

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K061598

Device Name: HemosIL Homocysteine and
HemosIL Homocysteine Controls

Indications for Use:

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HemosIL Homocysteine Controls are assayed quality controls intended to monitor the accuracy and precision of HemosIL Homocysteine on IL Coagulation Systems.

For *in vitro* diagnostic use.

Prescription Use √ (Part 21 CFR 801 Subpart D) **OR** Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional) K061598